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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,520	07/25/2005	Jean-Paul Remon	50304/083001	9447

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EXAMINER	
THEODORE, MAGALI P	
ART UNIT	PAPER NUMBER
1795	

NOTIFICATION DATE	DELIVERY MODE
04/01/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/536,520	REMON ET AL.	
	Examiner	Art Unit	
	Magali P. Théodore	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-57 and 60-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-57 and 60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/18/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's remarks filed December 18, 2009 were received.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 45, 47, 52-53 and 55-56 and 60 are rejected under 35 U.S.C. 102(b) as anticipated by Sugano et al. (US 4,416,606), henceforth **Sugano** or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Sugano** in view of Gamlen et al. (1986), henceforth **Gamlen**.

Regarding **claim 45**, Sugano teaches a continuous wet granulation method (1:5-7) comprising the steps of by feeding a powder (sodium percarbonate, 6:8) to a first transport zone (figure 1 zone I), feeding a liquid (aqueous solution, 6:11) into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (figure 1 zone II_1), transporting the mixture to a second transport zone further downstream (figure 1 zones II_2 *and III*) and discharging the resulting granules from the second transport zone through an aperture (figure 2:8).

Sugano's aperture is not collinear with the machine. However, it is the examiner's position that this is an obvious matter of engineering design that would have been obvious to one of ordinary skill in the art to modify. *Alternatively*, Gamlen teaches a discharge aperture (figure 1: [ex]trusion [p]late) collinear to the machine. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the collinear

position for the position of Sugano's aperture in order to achieve predictable results with a reasonable expectation of success.

Regarding **claim 46**, Sugano does not teach additional agglomeration or transport zones. However, it would have been obvious to one of ordinary skill in the art to duplicate those zones and the corresponding steps in order to effect more agglomeration. It has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See MPEPAGE 2144.04 VI B, in re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Regarding **claim 47**, Sugano teaches a twin screw (figure 1:2).

Regarding **claim 53**, Sugano teaches that the weight of the liquid is 1 % of the weight of the powder (2 liters of aqueous solution per 20 kg of powder equals 1 %, 6:10-13), which is away percentage point outside the claimed range of 2 % to 16 %. A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.

Regarding **claim 54**, Sugano does not specify an operating temperature. However, Sugano suggests that temperature as a result effective parameter by teaching cooling of the apparatus (4:61-64). Therefore it would have been obvious to one of ordinary skill in the art to optimize the operating temperature because Sugano teaches cooling. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claims 55-56**, Sugano teaches drying and dry-milling the discharged granules (5:11-16).

Regarding **claim 59**, Sugano does not teach the claimed liquid to powder ratio. However, this ratio is a result effective parameter because it determines the viscosity and friability of the mixture. If the mixture is too wet, it will not hold its shape; if the mixture is too dry, it will not hold together. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the liquid to powder ratio in the method taught by Sugano in order to control the mixture's viscosity and friability. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claim 60**, Sugano teaches avoiding a die or similar device by using a zero pressure gradient. The zero pressure gradient is inherent to the machine's open design (2:24).

Regarding **claims 61-64**, Sugano does not teach making tablets. However, Gamlen teaches making tablets from granules made by wet granulation (tabletting, page 1702 line 5). Therefore it would have been obvious to one of ordinary skill in the art to combine the step of making tablets with the steps taught by Sugano in order to achieve predictable results with a reasonable expectation of success.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Sugano**, or in the alternative, **Sugano** in view of **Gamlen** as applied to claim 45 above, and further in view of Harth et al. (US 6,174,851), henceforth **Harth**.

Regarding **claim 52**, Sugano does not teach any of the claimed substances. However, Sugano teaches that the powder is a sodium percarbonate (6:8), a bleaching agent (1:10-11) and Harth teaches conducting wet granulation (agglomeration, abstract first sentence) of a solid surfactant (7:15-18) combined with a solid percarbonate bleaching agent (7:43-44 and 7:50). The reason for granulating the surfactant and the percarbonate together is to produce a homogeneous "detergent" powder whose components do not separate with gravity (3:3-8 and 3:18-25). The surfactant alone can be considered a detergent in the chemical sense or the combination of surfactant and percarbonate can be called a detergent following common usage, e.g. laundry detergent. Therefore it would have been obvious to one of ordinary skill in the art add a detergent (surfactant) to the percarbonate powder taught by Sugano because Harth teaches granulating a surfactant together with percarbonate in order to make a homogeneous granule. *Alternatively*, it would have been obvious to one of ordinary skill in the art to combine a detergent (surfactant) with the percarbonate powder taught by Sugano in order to achieve predictable results with a reasonable expectation of success. *Alternatively*, it would have been obvious to one of ordinary skill in the art to substitute a detergent (surfactant plus percarbonate) for the percarbonate taught by Sugano in order to achieve predictable results with a reasonable expectation of success.

Claims 45-46, 48-51, 54, 57, 59-61 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gamlen** in view of **Sugano**.

Regarding **claim 45**, Gamlen teaches mixing powder and liquid (page 1705) and granulating the mixture to make pharmaceutical pills (page 1702 lines 3-7).

Gamlen's method involves the continuous (introduction, first line) extrusion of the mixture through a perforated plate (page 1705 lines 5-8). However, Sugano teaches that extruding the mixture through a perforated plate requires one to constantly replace the clogged plate (1:33-39). Sugano's remedy is a method comprising the steps of by feeding a powder (sodium percarbonate, 6:8) to a first transport zone (figure 1 zone I), feeding a liquid (aqueous solution, 6:11) into the same transport zone, continuously advancing the resulting mixture from the transport zone to an agglomeration zone downstream (figure 1 zone II_1), transporting the mixture to a second transport zone further downstream (figure 1 zones II_2 *and III*) and discharging the resulting granules through a wide aperture (2:8). Therefore it would have been obvious to one of ordinary skill in the art to replace the extrusion steps taught by Gamlen with the steps taught by Sugano because Sugano's steps eliminate the problem of the stopped-up extrusion plate.

Regarding the discharge aperture, Gamlen teaches a discharge aperture (figure 1: [ex]trusion [p]late) collinear to the machine. Sugano does not teach or suggest a rational for moving the *position* of the discharge aperture even while replacing the extrusion plate with a wide gap.

Regarding **claim 46**, Sugano does not teach additional agglomeration or transport zones. However, it would have been obvious to one of ordinary skill in the art to duplicate those zones and the corresponding steps in order to effect more agglomeration. It has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See MPEPAGE 2144.04 VI B, in re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Regarding **claim 48**, Gamlen does not specify a residence time. However, in any agitation process involving powder and liquid, powder needs time to absorb the liquid. Gamlen suggests that residence time is a result effective variable by proposing it as the object of further study (page 1713, Conclusion, part b). Therefore it would have been obvious to one of ordinary skill in the art to optimize the residence time of the mixture in the machine. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claims 49-51**, Gamlen teaches that the powder is about 80 % paracetamol, a poorly soluble analgesic.

Regarding **claim 54**, Gamlen does not specify an operating temperature. However, Gamlen suggests that temperature as a result effective parameter by teaching cooling of the mixture throughout the process (page 1705:10). Therefore it would have been obvious to one of ordinary skill in the art to optimize the operating temperature because Gamlen teaches constant cooling. Optimizing a result-effective

parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claim 57**, Gamlen teaches that the powder includes hydroxypropyl methyl cellulose (abstract line 4, page 1705 formula 2).

Regarding **claim 59**, Gamlen does not teach the claimed liquid to powder ratio. However, this ratio is a result effective parameter because it determines the viscosity and friability of the mixture. If the mixture is too wet, it will not hold its shape; if the mixture is too dry, it will not hold together. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the liquid to powder ratio in the method taught by Gamlen in order to control the mixture's viscosity and friability. Optimizing a result-effective parameter known in the art does not impart patentable distinction to an invention. See MPEPAGE 2144.05 [R-5] II, in re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding **claim 60**, Sugano teaches avoiding a die or similar device by using a zero pressure gradient. The zero pressure gradient is inherent to the machine's open design (2:24).

Regarding **claim 61** and **63-64**, Gamlen teaches making tablets (tabletting, page 1702 line 5).

Response to Arguments

Applicant's arguments, see pp. 11-13, filed December 18, 2009, with respect to Martin (2001) have been fully considered and are persuasive. The 103 rejections in view of Martin have been withdrawn.

Applicant's arguments with respect to claim 53 have been considered but are moot in view of the new ground(s) of rejection.

The remainder of Applicant's arguments filed December 18, 2009 have been fully considered but they are not persuasive.

Regarding Sugano, Applicant argues that the part of the machine with the open structure is Sugano's breaking zone III and not the downstream section of Sugano's kneading zone II. Applicant writes that on this basis alone, Sugano does not anticipate claim 45. From this statement, it is not clear to the examiner which specific limitation of amended claim 45 has not been met.

Applicant appears to argue that the examiner's combining Sugano's zones II and III to represent Applicant's second transport zone is improper. In response to Applicant's argument, the examiner has pointed to all the structural elements as they exist in Sugano; the examiner has simply given these structures different names in order to show how they correspond to Applicant's claims. There has been no reconstruction or reinterpretation of these structures or their functions.

Applicant argues that Sugano does not teach a zero pressure gradient. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the zero pressure gradient) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the 90 degree angle of Sugano's discharge port would create a pressure gradient. In response to Applicant's argument, the examiner indicates figure 2:8. The discharge port is so wide that the granules would simply fall out of the machine under gravity. The discharge port is so wide that it does not control the granules' sizes; they must be resized by a size adjusting machine (5:11-15). With this arrangement, there would be no pressure gradient.

Applicant argues that because Gamlen has technical deficiencies, it would not have been obvious to one of ordinary skill in the art to import any feature of Gamlen into Sugano's method. In response to Applicant's argument, Gamlen's technical deficiencies do not disqualify every aspect of Gamlen's method. Applicant has not shown that the collinear placement of the aperture is the source of any technical problems.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magali P. Théodore whose telephone number is (571) 270-3960. The examiner can normally be reached on Monday through Friday 9:00 a.m. to 6:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer K. Michener can be reached on (571) 272-1424. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Magali P. Théodore/
Examiner, Art Unit 1791

/Jennifer K. Michener/

Supervisory Patent Examiner, Art Unit 1795